



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,179	03/22/2001	Tae-Wan Kim	0609.4910002/JAG/JUK	8573

7590 11/30/2004

STERNE, KESSLER, GOLDSTEIN AND FOX, P.L.L.C.
1100 NEW YORK AVENUE, N.W.
SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	PAPER NUMBER

1647

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,179

Applicant(s)

KIM ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 10-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 9/27/04 has been entered into the record.
- B. Claims 1-41 are pending. Claims 10-40 have been withdrawn as being drawn to a non-elected invention.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. The rejection of claims 1-9 and 41 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite identifying a "candidate" agent that "potentiates" CCE.

3. Claim Rejections - 35 USC § 112, first paragraph – new matter

- A. The rejection of claims 1-9 and 41 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite "apoptotic" cell death.

4. Claim Rejections - 35 USC § 112, second paragraph

- A. The rejection of claims 1-9 and 41 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite that the agent "potentiates" CCE and adding the limitation that the animal studies are to test "toxicity or stability."

5. Claim Rejections - 35 USC § 103

- A. Claim 1 remains rejected under 35 USC 103 as being unpatentable over Berridge (Biochem J.) for the reasons already of record on page 4 of the Office Action mailed 7/2/04. Applicants argue that the Examiner previously acknowledged that Berridge "does not teach that 'CCE is linked to neurodegenerative diseases.'" Therefore, it would not have been obvious to Berridge to have used animal studies. This argument has been considered, but not deemed persuasive. While Berridge may not teach that CCE is linked to neurodegenerative diseases, this is not required by the present claims. Methods for assaying compounds for CCE modulation are taught in Berridge. It was well-known in the art at the time of the present invention to have used animal studies to further understand how candidate agents affect

Art Unit: 1647

systems more complex than individual cells. This is not argued by Applicants and even appear to agree in their present Response (“...merely because animal studies in general were known...”) Though Berridge may not make the link between CCE and animal studies, the present claims are only using animals for “toxicity or stability” testing, which is a well-known use of animal studies. **The claims do not require testing these agents in an animal model of neurodegenerative disease.** This is Applicants’ invention and this is what was not known in the art at that time. Toxicity and stability tests were well-known at the time. Therefore, Berridge, who teach the screening of agents which affect CCE, would meet the limitations of the present claims which, ultimately, do not require any knowledge of a link between CCE and neurodegenerative diseases.

A. Claim 1 remains rejected under 35 USC 103 as being unpatentable over Birnbaumer (U.S. 5,932,417) for the reasons already of record on pages 4-5 of the Office Action mailed 7/2/04 as well as for the reasons seen under Berridge. Applicants’ arguments are the same as those regarding Berridge. Therefore, the Examiner’s response is the same as for that rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1647

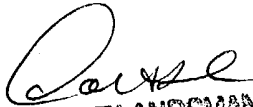
Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647


ROBERT LANDSMAN
PATENT EXAMINER